

IN THE UNITED STATES DISTRICT COURT  
FOR THE NORTHERN DISTRICT OF OHIO  
WESTERN DIVISION

IN RE: DEPUY ORTHOPEDICS, INC.,	)	MDL DOCKET NO. 1:10-cv-05785
ASR HIP IMPLANT PRODUCTS	)	MDL NO. 2197
LIABILITY LITIGATION	)	
This Document Relates To:	)	<b><u>STIPULATED EXPLANT</u></b>
ALL CASES	)	<b><u>PRESERVATION ORDER</u></b>

**EXPLANT PRESERVATION ORDER**

Upon the submissions of the parties and for good cause shown,

IT IS HEREBY ORDERED ADJUDGED AND DECREED that:

(1) Pursuant to the Court's duty to supervise pretrial proceedings in this case, including discovery, and pursuant to the Court's inherent power, the Court hereby orders, effective immediately, that DePuy Orthopaedics, Inc. ("Defendant") and Plaintiffs (collectively, "the Parties") shall comply with the following directives relating to the preservation of explants in the above-captioned matter:

**A. Definitions**

**Device Subject to This Order**

The provisions of this Order shall pertain to the following:

1. **DePuy ASR Device** means the ASR Hip System Device and components marketed and sold by Defendant in the United States.

2. Explanted DePuy ASR Device means the ASR Hip System Device and components explanted from patients in the United States, and tissue samples if retrieved during surgery. The provisions of this Order shall also pertain to any other DePuy ASR Devices that have been explanted and returned to Defendant that, through reasonable efforts, can be identified as having been implanted in any patients in the United States (hereinafter all referred to as "Explanted DePuy ASR Devices").

**B. Preservation Protocol**

The Parties agree that the Preservation Protocol, appended hereto as Exhibit A, represents a reasonable protocol designed for the preservation of Explanted DePuy ASR Devices and surrounding tissues which may constitute evidence related to any design or manufacturing claim which Plaintiffs may assert in this litigation. Defendant will not object to the request by or on behalf of a Plaintiff that the explanting surgeon and/or hospital retain and preserve synovial fluid and/or whole blood/serum pursuant to retention and preservation procedures to be established by and for that individual Plaintiff.

Recognizing that each explant procedure is within the purview and control of non-party medical practitioners and hospitals where surgeries occur, any departure from the attached Preservation Protocol by non-party medical practitioners and hospitals shall not constitute the spoliation of evidence by any of the Parties.

**C. Physical Evidence**

The Parties shall make good faith efforts with non-party medical practitioners and hospitals to preserve any Explanted DePuy ASR Devices within their possession, custody or control that may be relevant to the claims, defenses, or subject matter of this litigation. Defendant will not take steps which inhibit requests by or on behalf of a Plaintiff to have their surgeon and/or hospital retain and preserve any Explanted DePuy ASR Device, synovial fluid, and/or whole blood/serum or any other physical evidence.

**1. Non-Destructive Inspection and Analysis.**

Non-destructive inspection and analysis by the Parties or their designated contract laboratory(s) of Explanted DePuy ASR Devices are allowed. The Parties agree that the "Procedure for Laboratory Inspection of ASR, ASR-XL and Related Components" ("Inspection Protocol"), one of the Preservation Protocols appended hereto as Exhibit A, represents a reasonable non-destructive protocol designed for the inspection of Explanted DePuy ASR Devices which may constitute evidence related to any design or manufacturing claim which Plaintiffs may assert in this litigation. The Parties will not object to any inspection of Explanted DePuy ASR Devices which is reasonably consistent with the Inspection Protocol, and this Order, and any inspection of Explanted DePuy ASR Devices which is reasonably consistent with the Inspection Protocol, and this Order, shall not constitute the spoliation of evidence by any of the Parties. If counsel of record for a Plaintiff so chooses, a Plaintiff's Explanted DePuy ASR Device may be obtained from the Plaintiff's surgeon or the hospital where the surgery occurred and sent to a contract laboratory(s) of Plaintiff's choice, or a designated storage facility, subject to the requirement that the explant shall be preserved in accordance with the attached

Preservation Protocol and inspection and analysis shall be non-destructive, and reasonably consistent with the attached Inspection Protocol, and this Order. Absent that choice by counsel of record for a Plaintiff, DePuy will make arrangements for Explanted DePuy ASR Devices to be sent to Orthopaedic Hospital, Los Angeles, California, with the requirement that the explant shall be preserved in accordance with the attached Preservation Protocol and inspection and analysis shall be non-destructive, and reasonably consistent with the attached Inspection Protocol, and this Order. Except as permitted in the attached Preservation Protocol and Inspection Protocol, the parties will take reasonable measures with their respective contract laboratories and/or designated storage facilities to maintain the Explanted DePuy ASR Devices, including all component parts, in the same condition as they were in when received, including refraining from altering the structure, existence, integrity and nature of the device surfaces as explanted. Except as otherwise permitted by this Order, all Explanted DePuy ASR Devices obtained by the Parties from surgeons or from the hospital where a Plaintiff's surgery occurred shall be retained by the receiving party, its designated contract laboratory(s) or designated storage facility unless otherwise agreed by the Parties.

**2. Surgically Removed DePuy ASR Device in Plaintiffs' or Defendant's Possession**

In the event that prior to the entry date of this Order, an Explanted DePuy ASR Device has been obtained by either Plaintiffs or Defendant, the Parties agree as follows:

- (i) For each Plaintiff who has obtained an Explanted DePuy ASR Device, notice of that fact will be provided to Defendant, along with information as to the date of the explantation, the location of the explant, whether synovial fluid and/or whole blood/serum were retained, and

an acknowledgement that the explant will be preserved, and that any further inspection and testing shall be in accordance with the provisions of this Order and the attached Preservation Protocol.

(ii) For each Plaintiff for whom DePuy may have obtained an Explanted DePuy ASR Device, notice of that fact will be provided to Plaintiff's Counsel of record, along with information as to the date of the explantation, the location of the explant, and an acknowledgement that the explant will be preserved, and that any further inspection and testing shall be in accordance with the provisions of this Order and the attached Preservation Protocol. Upon request, DePuy will return the explant to Plaintiff's counsel of record upon receipt of an acknowledgement that the explant will be preserved, inspected and tested in accordance with the provisions of this Order and the attached protocols. If the request for forwarding arrives prior to the completion of the testing and inspection, then (a) the inspection shall stop immediately and (b) the DePuy Laboratory shall seek approval to either complete the inspection or will forward the device as requested. If a Plaintiff's Explanted DePuy ASR Device was obtained prior to the entry of this Order, and has been inspected or tested, the results of such inspection and testing shall be made available to counsel of record for the opposing party. The Parties agree that the mere failure to follow the Preservation Protocol attached to this Order for such Explanted DePuy ASR Devices received prior to the entry of this Order shall not constitute the spoliation of evidence.

**D. Inspection Results**

The Parties agree to exchange the results of all inspection and testing done by their respective contract laboratory(s) on all Explanted DePuy ASR Devices, including the exchange of all data generated as a result of the inspection and testing, photographs, and other information generated as a result of the inspection and testing Preservation Protocol attached to this Order.

**1. For Defendant Obtained Explanted DePuy ASR Devices**

For Explanted DePuy ASR Devices obtained from surgeons or hospitals by Defendant, upon request and after the completion of the inspection and testing by Defendant's contract laboratory, Plaintiff has the right, at their expense, to request that their Explanted DePuy ASR Device be sent to a contract laboratory of Plaintiff's choice for further inspection and testing. Plaintiff is entitled to receive the results of the inspection and testing performed by or at the request of Defendant, including the exchange of all data generated as a result of the inspection and testing, photographs, and other information generated as a result of the inspection. Defendant is entitled to receive the results of the inspection and testing performed at the request of Plaintiff, including the exchange of all data generated as a result of the inspection and testing, photographs, and other information generated as a result of the inspection.

**2. For Plaintiff Obtained Explanted DePuy ASR Devices**

For Explanted DePuy ASR Devices obtained from surgeons or hospitals by Plaintiff, upon request and after the completion of the inspection and testing by Plaintiff's contract laboratory, Defendant has the right, at their expense, to request that the Explanted DePuy ASR Device and synovial fluid and/or whole blood/serum, if retained, and if any remains after Plaintiff's testing, be sent to a contract laboratory of Defendant's choice for further inspection

and testing. Defendant is entitled to receive the results of the inspection and testing performed at the request of Plaintiff, including the exchange of all data generated as a result of the inspection and testing, photographs, and other information generated as a result of the inspection, including any information or data from the testing of synovial fluid and/or whole blood/serum. Plaintiff is entitled to receive the results of the inspection and testing performed by or at the request of Defendant, including the exchange of all data generated as a result of the inspection and testing, photographs, and other information generated as a result of the inspection.

(i) If Plaintiff has taken possession of an Explanted DePuy ASR Device and has chosen not to conduct an inspection or testing, Defendant shall have the right to request that the Explanted DePuy ASR Device be sent to a contract laboratory of Defendant's choice for inspection and testing. Plaintiff is entitled to receive the results of the inspection and testing, including the exchange of all data generated as a result of the inspection and testing, photographs, and other information generated as a result of the inspection. Upon completion of Defendant's inspection and testing, Plaintiff shall be entitled to have the Explanted DePuy ASR Device sent to a contract laboratory of Plaintiff's choice for further inspection and testing, with Defendant entitled to receive the results of the inspection and testing, including the exchange of all data generated as a result of the inspection and testing, photographs, and other information generated as a result of the inspection.

**E. Dissemination of this Order**

Defendant shall disseminate this Order to surgeons and hospital representatives who were recipients of its letter dated September 30, 2010, regarding "Retention of Explanted Components," and in addition to distributors of Defendant's ASR Device with a request that the

distributors disseminate to its representatives, and by doing so, shall be deemed to have satisfied the Court's expectation that this Order be communicated to non-party medical practitioners and hospitals.

The Parties agree that neither will promote or encourage third parties, including but not limited to physicians and hospital personnel, to act in a way that is inconsistent with this Order or the Preservation Protocols.

**F. Court Oversight of the Process**

The process of obtaining from surgeons and hospitals Explanted DePuy ASR Devices, and then sending for inspection, and testing hundreds if not thousands of Explanted DePuy ASR Devices at contract laboratories, is likely to encounter complications which the Parties and this Court cannot anticipate at this time. The Court shall retain an active involvement in this process and the Parties shall keep the Court advised of complications encountered. In the event that a dispute arises between a hospital and a Patient or Patient's counsel regarding the retrieved components, the Patient or Patient's counsel has a right to seek relief in this Court and this Court will intervene to resolve this dispute. To facilitate the Court's involvement in resolving any complications arising from this Order, the Court designates Plaintiff's Executive Committee member Eric Kennedy (216.781.111, [ekennedy@weismanlaw.com](mailto:ekennedy@weismanlaw.com)) and Defense Counsel Bob Tucker (216.696.4093, [robert.tucker@tuckerellis.com](mailto:robert.tucker@tuckerellis.com)) as the contact persons who will field any questions and who will bring to the Court those issues requiring Court involvement.

IT IS SO ORDERED

Judge David A. Katz

Dated

April 5, 2011

AGREED:

Counsel for Plaintiffs' Executive Committee

M. C. R.  
Counsel for Defendant

Date

4. 5. 11

Date

April 5, 2011